said second outer tube comprises a radiopaque material;

said wire coil is of flat wire;

said first and second outer tubes are bonded to said inner tube and to said wire coil.

REMARKS

This paper is responsive to the Office Action mailed May 16, 2002. Presently, claims 1-21 stand rejected.

Claims 1-21 were rejected under 35 U.S.C.§112, first paragraph. In response, Applicant has amended each of claims 1-21 as suggested by the Examiner to indicate that the claims are directed to an "introducer sheath" rather than to an "intravascular sheath."

Claim 10 was rejected under 35 U.S.C. §112, second paragraph as having insufficient antecedent basis. This claim has been amended in the manner suggested by the Examiner.

Claims 1-2, 4-5, 10-13 and 15-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187). As noted by the Examiner in the Office Action, Horrigan does not teach the use of a wire coil to offer kink resistance. Rather, Horrigan teaches the use of a wire braid reinforcement. Fig. 8 of Park teaches the use of a wire coil (236 in Fig. 8). According to the Examiner, it would have been obvious to substitute the wire coil of Park for the wire braid of Horrigan which would "involve mere substitution of one functional equivalent for another" and that "the selection of any of these known equivalents would provide a catheter section with improved kink resistance as taught by Horrigan et al." Applicant respectfully traverses this rejection.

The present invention is directed to an introducer sheath. Optimally, such sheaths should have a thin-walled construction and be resistant to kinking. When an introducer sheath kinks during a medical procedure the sheath becomes unusable and cannot be straightened. As a result, the sheath must be removed, thereby leaving an enlarged, bleeding opening which typically cannot be reused for percutaneous entry. Increasing the thickness of the sheath wall in an attempt to avoid kinking is undesirable because the increased wall thickness reduces the ability of the sheath to pass through narrow bodily passageways. In

addition, this increased wall thickness necessitates enlargement of the entry hole, which is also undesirable.

The cited Horrigan patent teaches a guiding catheter for use in PTCA. According to the patent specification, it is an important characteristic of such catheters that they have sufficient stiffness to be pushed through vessels, as well as sufficient rigidity to provide a high degree of torsional control. Col. 1, lines 15-21. In Horrigan, an inner PTFE liner is reinforced by fusing a wire braid along the outer diameter of the PTFE liner. The braid terminates a few millimeters proximal to the distal end of the liner. Col. 4, lines 18-25.

It is well-known that a desirable feature of an introducer sheath is that it be thin-walled. Nevertheless, Horrigan chose to utilize a wire braid fused to the inner liner as a reinforcement means, rather than a wire coil as in the present invention. It is well known in the art that the use of a wire braid reinforcement provides favorable torsional control when compared to a wire coil (torsional control being a stated objective of Horrigan). However, it is also well known that a wire braid enjoys little kink resistance when compared to a wire coil. The problem of kink resistance is not addressed in the Horrigan patent. In addition to the lack of kink resistance, a braided reinforcement also has an enlarged diameter when compared to a wire coil. This results from the crossing of the wire strands that make up the braided pattern. For example, when wire having a 0.002 inch diameter is used, the effective diameter of the windings of a coil made of such wire is 0.002 inch. Since a braid includes crossings of this wire, the effective diameter at the crossings of a braid made of such wire is 0.004 inch, or twice that of the wire coil. When a key objective of such introducer sheaths is to achieve smaller and smaller diameters, the use of a wire coil is advantageous. Thus, with regard to the desirable characteristics of kink resistance and wall diameter, an introducer sheath utilizing a wire coil enjoys two key advantages over a wire braid.

In addition to the foregoing, yet another advantage of the use of a wire coil in an introducer sheath relates to the ease of manufacture of the sheath. When a braid is utilized, it is necessary to fuse or otherwise bond (at least) the ends of the braid to the inner liner. Otherwise, the high tensile strength of the braid tends to cause the braid to spring outwardly and not wrap around the liner. In addition, the terminal ends of a braid are prone to fraying,

This necessitates that the ends of the braid be well-bonded or fused to the outer wall of the inner liner to avoid such frayed ends. A wire coil, on the other hand, may simply be compression fitted around the inner liner within the outer tube. Normally, no fusing or bonding of the coil, or its ends, is required. Thus, the use of a wire coil reinforcement rather than a wire braid in an introducer sheath reduces the costs of manufacture of the sheath.

The Park reference teaches a catheter section that is capable of self-forming a selected shape upon application of heat. Specifically, the catheter section includes a forming member which comprises a super-elastic nickel-titanium (nitinol) alloy. The super-elastic alloy is used because of its ability to retain non-elastic strain and return to a prior form upon release of the polymeric restraint.

As stated, the present invention utilizes a wire coil rather than a wire braid, to obtain the advantages of, among others, kink resistance, small wall diameter and low manufacturing cost. The Horrigan reference neither teaches nor suggests an optimal manner of achieving such advantages, and in fact, teaches away from such advantages. Park teaches the use of a super-elastic nickel-titanium alloy reinforcement composition. Although use of such an alloy provides shape-forming and memory advantages not present in otherwise-comparable reinforcement devices, such alloys add a degree of complexity and cost to the catheter that is not warranted in all instances. Although this reference mentions that kink-resistance is a desirable feature of such catheters, it does not teach or suggest the straightforward manner in which such problem is addressed in the present invention. In addition, Park does not teach or suggest the advantages of small diameter and cost manufacturing advantages of the present invention. Applicant respectfully submits that absent the use of hindsight gleaned from the teachings of the present invention, one skilled in the art would not combine such disparate teachings to arrive at the claimed invention.

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Parker (US 5,380,384). Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju et al (US

5,599,325). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of MacDonald et al (US 6,210,396).

According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. MacDonald was cited for its teaching of an outer tube comprising first and second tube sections of different colors. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1.

Based upon the foregoing, Applicant respectfully submits that all claims 1-21 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,

Lawrence A. Steward
Atty. No. 32,309

LAS/cbw

BRINKS HOFER GILSON & LIONE
One Indiana Square, Suite 2425
Indianapolis, Indiana 46204
Phone: (317) 636-0886
Fax: (317) 634-5701

MARKED UP COPY OF CLAIMS

1. (Amended) An [intravascular] introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end;

a first outer tube disposed around said wire coil and said inner tube therewithin to a first outer tube distal end spaced proximally from said wire coil distal end such that a distal end portion of said wire coil extends distally therebeyond; and

at least a second outer tube disposed around said wire coil and said inner tube therewithin extending distally from said first outer tube distal end and covering said distal end portion of said wire coil and extending slightly beyond said distal end of said inner tube,

said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material of a substantially softer durometer than said material of said first outer tube.

2. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said outer tube and said inner tube are bonded to each other and to said wire coil and to said inner tube between windings of said wire coil.

3. (Amended) The [intravascular] introducer sheath according to claim 2, wherein an outwardly facing surface of said inner tube has been roughened to enhance bonding thereto of said first and second outer tubes.

4. (Amended) The [intravascular] introducer sheath according to claim 2, wherein said bonding is heat bonding.

5. (Amended) The [intravascular] introducer sheath according to claim 1, wherein a radiopaque marker band is affixed to said wire coil distal end within said second outer tube.

6. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said second outer tube is polymeric and contains radiopaque filler.

7. (Amended) The [intravascular] introducer sheath according to claim 6, wherein said second outer tube contains between about 20% and 85% by weight of radiopaque filler particles.

8. (Amended) The [intravascular] introducer sheath according to claim 6, wherein said second outer tube contains about 80% by weight of radiopaque filler particles.

9. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said first outer tube is substantially free of radiopaque filler.

10. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of at least 5 D lower than that of the material of the first outer [tubing length] tube.

11. (Amended) The [intravascular] introducer sheath according to claim 10, wherein said first outer tube comprises a material having a durometer of about 56D to 58D.

12. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of between about 10 D and 75 D.

13. (Amended) The [intravascular] introducer sheath according to claim 12, wherein said second outer tube comprises a material having a durometer of about 39D.

14. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said first and second outer tubes are distinctly different in color or shade.

15. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said wire coil comprises flat wire.

16. (Amended) The [intravascular] introducer sheath according to claim 1, wherein a distal tip region of the sheath is arcuate.

17. (Amended) The [intravascular] introducer sheath according to claim 16, wherein said arcuate distal tip region has a length of about 1 cm or more.

18. (Amended) The [intravascular] introducer sheath according to claim 16, wherein said arcuate distal tip region extends about an angle of about 90°.

19. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said wire coil extends for a length of about five millimeters beyond said distal end of said first outer tube.

20. (Amended) The [intravascular] introducer sheath according to claim 1, wherein said inner tube is unitarily formed.

21. (Amended) An [intravascular] introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end;

a first outer tube disposed around said wire coil and said inner tube therewithin to a first outer tube distal end spaced proximally from said wire coil distal end such that a distal end portion of said wire coil extends for a length of about 1 cm distally therebeyond; and

a second outer tube distally from said first outer tube distal end and disposed around and covering said distal end portions of said wire coil and said inner tube therewithin and extending slightly therebeyond;

said first outer tube being of a material having a durometer of between about 50 D and 60 D, and said second outer tube being of a material of a durometer of between about 35 D and 45 D;

said second outer tube comprises a radiopaque material;

said wire coil is of flat wire;

said first and second outer tubes are bonded to said inner tube and to said wire coil.